PCT/JP2003/004445

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference ZP0041	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP2003/004445	International filing date (*day/month/year*) 08 April 2003 (08.04.2003)	Priority date (*day/month/year*) 08 April 2002 (08.04.2002)
International Patent Classification (IPC) or national classification and IPC A61K 31/426, A61P 1/00, C07D 277/56		
Applicant ZERIA PHARMACEUTICAL CO., LTD.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
28 August 2003 (28.08.2003)	13 January 2004 (13.01.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

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International application No.
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I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the claims:

pages _____, as originally filed

pages _____, as amended (together with any statement under Article 19

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 9-12

because:

☒ the said international application, or the said claims Nos. 9-12 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

The inventions of claims 9-12 concern a method for treating the human body by therapy, which does not require an international preliminary examination by the International Preliminary Examining Authority in accordance with PCT Article 34(4)(a)(i) and Rule 67.1(iv).

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 9-12.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims		YES
	Claims	1-8	NO
Inventive step (IS)	Claims		YES
	Claims	1-8	NO
Industrial applicability (IA)	Claims	1-8	YES
	Claims		NO

2. Citations and explanations

Document 1: EP 870765 A1 (ZERIA PHARMACEUTICAL CO., LTD.) October 14, 1998
Document 2: JP 10-212271 A (ZERIA PHARMACEUTICAL CO., LTD.) August 11, 1998
Document 3: EP 994108 A1 (ZERIA PHARMACEUTICAL CO., LTD.) April 19, 2000
Document 4: WO 02/20010 A1 (ZERIA PHARMACEUTICAL CO., LTD.) March 14, 2002
Document 5: MORITA, H., "Possible involvement of M5 muscarinic receptor in the enhancing actions of the novel gastroprokinetic agent Z-338 on nifedipine-sensitive voltage-dependent Ca2+ currents in guinea pig stomach"
Japanese Journal of Pharmacology (2002), Vol. 89, No. 4, pp. 356-365
Document 6: KANEMOTO, Y., "An electrophysiological study of muscarinic and nicotinic receptors of rat paratracheal ganglion neurons and their inhibition by Z-338"
British Journal of Pharmacology (2002), Vol. 135, No. 6, pp. 1403-1414
Document 7: OGISHIMA, M., "Z-338 facilitates acetylcholine release from enteric neurons due to blockade of muscarinic autoreceptors in guinea pig stomach"
Journal of Pharmacology and Experimental Therapeutics (2000), Vol. 294, No. 1, pp. 33-37
Document 8: NAKAMIMA, T., "Z-338, a newly synthesized carboxyamide derivative, stimulates gastric motility through enhancing the excitatory neurotransmission"
Journal of Smooth Muscle Research (2000), Vol. 36, No. 2, pp. 69-81
Document 9: FURUTA, S., "LC determination of Z-338, novel gastroprokinetic agent in god plasma by SCX solid phase extraction"
Journal of Pharmaceutical and Biomedical Analysis (2001), Vol. 25, No. 3-4, pp. 599-603

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V:

Based on the descriptions in documents 1-8 cited in the international search report, the inventions of claims 1-8 lack novelty and an inventive step.

Documents 1-9 state that 2-[N-(4,5-dimethoxy-2-hydroxy benzoyl) amino]-4-[(2-diisopropyl amino ethyl) amino carbonyl]-1,3-thiazole is useful for the prevention and treatment of generalized epigastric complaints, feelings of abdominal bloating, etc. (document 1, claims and page 10; document 2, claims and column 42; document 3, page 1; document 4, page 3; document 5, pages 356 to 365; document 6, pages 1403 to 1414; document 7, pages 33 to 37; document 8, pages 69 to 81; document 9, pages 599 to 603).

Gastric food competence is not specifically disclosed in documents 1-9, but the drugs used for the treatment of gastric food competence disorder in this application are also used for the prevention and treatment of feelings of early satiety and abdominal bloating, etc., and they are indistinguishable with respect to therapeutic use from drugs used for the treatment of generalized epigastric complaints and feelings of abdominal bloating, etc., which is the scope of application of existing drugs.

As a result, the inventions described in claims 1-8 are one and the same as the inventions described in documents 1-9.